

CLAIMS

- 5 1. A pharmaceutical composition comprising an NO-releasing amount of the R(+) enantiomer of amlodipine or of a pharmaceutically acceptable salt thereof, an anti-hypertensive amount of the S(-) enantiomer of amlodipine or of a pharmaceutically acceptable salt thereof and a suitable excipient, diluent, or carrier, wherein the enantiomers are present in a ratio by weight (based on free base) of R(+) enantiomer : S(-) enantiomer of greater than 1:1.
- 10 2. A pharmaceutical composition according to Claim 1 wherein said ratio is less than 10:1.
- 15 3. A pharmaceutical composition according to Claim 1 wherein said ratio is in the range 2:1 to 8:1.
- 20 4. A pharmaceutical composition according to Claim 1 wherein said ratio is approximately 5:1.
- 25 5. A pharmaceutical composition according to Claim 1 which comprises a mixture of single crystals of the R(+) enantiomer or pharmaceutically acceptable salt thereof and single crystals of the S(-) enantiomer or pharmaceutically acceptable salt thereof.
- 30 6. A pharmaceutical composition according to Claim 5 wherein both enantiomers are in the form of pharmaceutically acceptable salts.
7. A pharmaceutical composition according to Claim 6 wherein the salts of both enantiomers have the same counter ion.
8. A pharmaceutical composition according to Claim 1 which comprises single crystals of the R(+) enantiomer or pharmaceutically acceptable

salt thereof and mixed crystals containing both the R(+) enantiomer and the S(-) enantiomer or pharmaceutically acceptable salts of one or both thereof.

- 5 9. A pharmaceutical composition according to Claims 8 wherein the mixed crystals are racemic.
- 10 10. A pharmaceutical composition according to Claims 8 or 9 wherein the R(+) enantiomer is in the form of a pharmaceutically acceptable salt and the enantiomers in the mixed crystals are also in the form of pharmaceutically acceptable salts.
- 15 11. A pharmaceutical composition according to Claims 8 or 9 wherein the salt of the R(+) enantiomer and the salts of the enantiomers in the mixed crystals have the same counter ion.
- 20 12. A pharmaceutical composition according to Claim 11 which comprises mixed crystals containing both the R(+) enantiomer or pharmaceutically acceptable salt thereof and the S(-) enantiomer or pharmaceutically acceptable salt thereof.
- 25 13. A pharmaceutical composition according to Claim 12 wherein both enantiomers are in the form of pharmaceutically acceptable salts.
- 30 14. A pharmaceutical composition according to Claim 13 wherein the salts of both enantiomers have the same counter ion.
15. A pharmaceutical composition according to Claim 7 wherein said counter ion is mesylate or succinate.
16. A pharmaceutical composition according to Claim 11 wherein said counter ion is mesylate or succinate.

17. A pharmaceutical composition according to Claim 14 wherein said counter ion is mesylate or succinate.
- 5 18. A pharmaceutical composition according Claim 1 which is in the form of a tablet or capsule suitable for oral administration.
19. A pharmaceutical composition according Claim 1 which is in liquid dosage form.
- 10 20. A pharmaceutical composition according to Claim 1 which is in the form of a solution suitable for intravenous (iv) administration.
- 15 21. A process for the preparation of a composition according to Claim 5 wherein single crystals of the R(+) enantiomer or pharmaceutically acceptable salt thereof are mixed in the desired ratio with single crystals of the S(-) enantiomer or pharmaceutically acceptable salt thereof.
- 20 22. A process for the preparation of a composition according to Claim 6 wherein single crystals of the R(+) enantiomer or pharmaceutically acceptable salt thereof are mixed in the desired ratio with single crystals of the S(-) enantiomer or pharmaceutically acceptable salt thereof.
- 25 23. A process for the preparation of a composition according Claim 7 wherein single crystals of the R(+) enantiomer or pharmaceutically acceptable salt thereof are mixed in the desired ratio with single crystals of the S(-) enantiomer or pharmaceutically acceptable salt thereof.
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24. A process for the preparation of a composition according to Claim 8 wherein single crystals of the R(+) enantiomer or pharmaceutically acceptable salt thereof are mixed in the desired ratio with crystals containing both the R(+) enantiomer and the S(-) enantiomer or pharmaceutically acceptable salts of one or both thereof.
25. A process for the preparation of a composition according to Claim 12 wherein mixed crystals containing both the R(+) enantiomer and the S(-) enantiomer or pharmaceutically acceptable salts of one or both thereof in the desired ratio are formed by co-crystallization.
26. The R(+) enantiomer of amlodipine or a pharmaceutically acceptable salt thereof for use in the treatment of a condition for which a vascular NO-releasing agent is indicated.
27. A method for manufacture of a medicament for the treatment of a condition for which a vascular NO-releasing agent is indicated comprising incorporating R(+) enantiomer of amlodipine or of a pharmaceutically acceptable salt thereof into a formulation suitable for administration to a patient.
28. The method according to Claim 27 wherein said medicament is a pharmaceutical composition comprising an NO-releasing amount of the R(+) enantiomer of amlodipine or of a pharmaceutically acceptable salt thereof, an anti-hypertensive amount of the S(-) enantiomer of amlodipine or of a pharmaceutically acceptable salt thereof and a suitable excipient, diluent, or carrier, wherein the enantiomers are present in a ratio by weight (based on free base) of R(+) enantiomer : S(-) enantiomer of greater than 1:1.

29. A pharmaceutical composition according to Claim 1 for use in the treatment of a condition for which a vascular NO-releasing agent is indicated.
- 5 30. A method of treating a condition for which a vascular NO-releasing agent is indicated which comprises the administration of a pharmaceutical composition in accordance with Claim 1.
- 10 31. A method for the manufacture of a medicament for the treatment of a condition for which both an anti-hypertensive agent and a vascular NO-releasing agent are indicated comprising incorporating the R(+) enantiomer of amlodipine or of a pharmaceutically acceptable salt thereof into a formulation suitable for administration to a patient.
- 15 32. The method of claim 31 wherein said medicament is a pharmaceutical composition comprising an NO-releasing amount of the R(+) enantiomer of amlodipine or of a pharmaceutically acceptable salt thereof, an anti-hypertensive amount of the S(-) enantiomer of amlodipine or of a pharmaceutically acceptable salt thereof and a suitable excipient, diluent, or carrier, wherein the enantiomers are present in a ratio by weight (based on free base) of R(+) enantiomer : S(-) enantiomer of greater than 1:1.
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- 25 33. A pharmaceutical composition according to Claim 1 suitable for use in a treatment of a condition for which both an anti-hypertensive and a vascular NO-releasing agent are indicated.
- 30 34. A method of treating a condition for which both an anti-hypertensive agent and a vascular NO-releasing agent are indicated which comprises the administration of a pharmaceutical composition in accordance with Claim 1.

35. A pharmaceutical composition comprising an NO-releasing amount of the R(+) enantiomer of amlodipine or of a pharmaceutically acceptable salt thereof, an NO-inducing amount of an ACE inhibitor and a suitable excipient, diluent, or carrier.
36. A composition according to Claim 35 wherein said ACE inhibitor is ramaprilat or quinapril.
37. A pharmaceutical composition comprising an NO-releasing amount of the R(+) enantiomer of amlodipine or of a pharmaceutically acceptable salt thereof, an NO-potentiating amount of a PDE5 inhibitor and a suitable excipient, diluent, or carrier.
38. A composition according to Claim 37 wherein said PDE5 inhibitor is sildenafil.